

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER

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1029/188

09/051290

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.

PCT/FR96/01573

INTERNATIONAL FILING DATE

9 October 1996

PRIORITY DATE CLAIMED

9 October 1995

TITLE OF INVENTION

NEEDLELESS JET INJECTION DEVICE COMPRISING A MOULDED-ON CARTRIDGE

APPLICANT(S) FOR DO/EO/US

MOREAU DEFARGES, Alain and MOREAU DEFARGES, Xavier

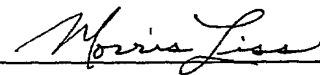
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

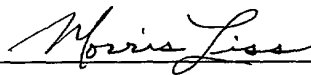
1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. § 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as **published** (35 U.S.C. 371(c)(2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☒ An amended specification incorporating amended pages 2-2b and 12-14.
15. ☐ A change of power of attorney and/or address letter
16. ☒ Other items or information:

A copy of the PCT Request
A copy of the International Preliminary Examination Report
A copy of PCT/IB/308
A copy of PCT/IB/301
A copy of PCT/IB/304

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO. PCT/FR96/01573		ATTORNEY'S DOCKET NUMBER 1029/168	
<input checked="" type="checkbox"/> The following fees are submitted: Basic National Fee (37 CFR 1.492(a)(1)-(5)): Search Report has been prepared by the EPO or JPO \$930.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) \$720.00 No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$790.00 Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$1,070.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$98.00 ENTER APPROPRIATE BASIC FEE AMOUNT = \$930.00				CALCULATIONS	PTO USE ONLY
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$130.00	
Claims	Number Filed	Number Extra	Rate		
Total Claims	12 - 20 = 0		X \$22.00	\$0.00	
Independent Claims	1 - 3 = 0		X \$82.00	\$0.00	
Multiple dependent claim(s)(if applicable)			+ \$270.00	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,060.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28)				\$	
SUBTOTAL =				\$1,060.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$0.00	
TOTAL NATIONAL FEE =				\$1,060.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$0.00	
TOTAL FEES ENCLOSED =				\$1,060.00	
				Amount to be: refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$1,060.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. <u>22-0185</u> in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>22-0185</u> . A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status SEND ALL CORRESPONDENCE TO:					
Pollock, Vande Sande & Priddy, R.L.L.P. 1990 M Street, N.W. Suite 800 Washington, DC 20036-3425			 SIGNATURE <u>Morris Liss</u> NAME <u>24,510</u> REGISTRATION NUMBER		

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 1		INTERNATIONAL APPLICATION NO. PCT/FR96/01573		ATTORNEY'S DOCKET NUMBER 1029/168	
<input checked="" type="checkbox"/> The following fees are submitted: Basic National Fee (37 CFR 1.492(a)(1)-(5)): Search Report has been prepared by the EPO or JPO \$930.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) \$720.00 No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$790.00 Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$1,070.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$98.00 ENTER APPROPRIATE BASIC FEE AMOUNT = \$930.00				CALCULATIONS	PTO USE ONLY
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Claims	Number Filed	Number Extra	Rate		
Total Claims	12 - 20 = 0		X \$22.00	\$0.00	
Independent Claims	1 - 3 = 0		X \$82.00	\$0.00	
Multiple dependent claim(s)(if applicable)			+ \$270.00	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,060.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28)				\$	
SUBTOTAL =				\$1,060.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$0.00	
TOTAL NATIONAL FEE =				\$1,060.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$0.00	
TOTAL FEES ENCLOSED =				\$1,060.00	
				Amount to be: refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$1,060.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 22-0185 in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 22-0185 . A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status SEND ALL CORRESPONDENCE TO:					
Pollock, Vande Sande & Priddy, R.L.L.P. 1990 M Street, N.W. Suite 800 Washington, DC 20036-3425			 SIGNATURE Morris Liss NAME 24,510 REGISTRATION NUMBER		

09/051290

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
	:	
Alain Moreau Defarges et al.	:	
	:	
Serial No. To be assigned	:	Art Unit: To be assigned
	:	
Filed: Herewith	:	Examiner: To be assigned
	:	
For: NEEDLELESS JET	:	Atty Docket: 1029/168
INJECTION DEVICE	:	
COMPRISING A	:	
MOULDED-ON CARTRIDGE	:	
	:	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified national phase application, please enter the following amendments to the amended specification submitted for examination herewith:

IN THE ABSTRACT

Please add the Abstract of the Disclosure attached hereto on a separate sheet.

IN THE CLAIMS

Kindly amend claims (from amended sheets 12-14) 5, 7, 9, and 12 as follows:

5. (Amended) Injection cartridge according to [any one of the preceding claims, characterized in that it includes] claim 1, further including, at one of its ends, means (51) permitting the engagement and fixing of the said cartridge on the nose of the injection device.

7. (Amended) Injection cartridge according to [any one of the preceding claims, characterized in that the] claim 1, further comprising an end (54) of the cartridge (28) that is covered by a cap (55) provided at its [centre] center with an elastomeric seal (56), in particular of silicone.

9. (Amended) Injection cartridge according to [one of the Claims 7 and 8, characterized in that the] claim 7, wherein an upper wall (60) of the cap (55) forms a grip zone which allows the user to position the studs (52) of the cartridge (28) in line with the bayonets of the injection device.

12. (Amended) Injection cartridge according to [any one of the preceding claims, characterized in that it includes] claim 1, further including a plurality of plastic material gaps, formed in the thickness of the plastic overmould of the cartridge (28), in order to produce slots (63) for improving the visibility of the first element (49).

REMARKS

Claims 1-12 remain in the application. By the foregoing amendment, claims 5, 7, 9, and 12 have been amended to remove multiple dependencies and improper multiple dependencies and to improve the English wording thereof.

In addition, an Abstract has been provided to bring the application into full compliance with 37 CFR § 1.72(b).

These changes are not believed to introduce new matter, and entry of this amendment is respectfully requested.

DEPOSIT ACCOUNT AUTHORIZATION

It is not believed that extensions of time or fees for net addition of claims are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary, then such extensions of time are hereby petitioned under 37 CFR § 1.136(a), and any fees required for consideration of this paper, including fees for

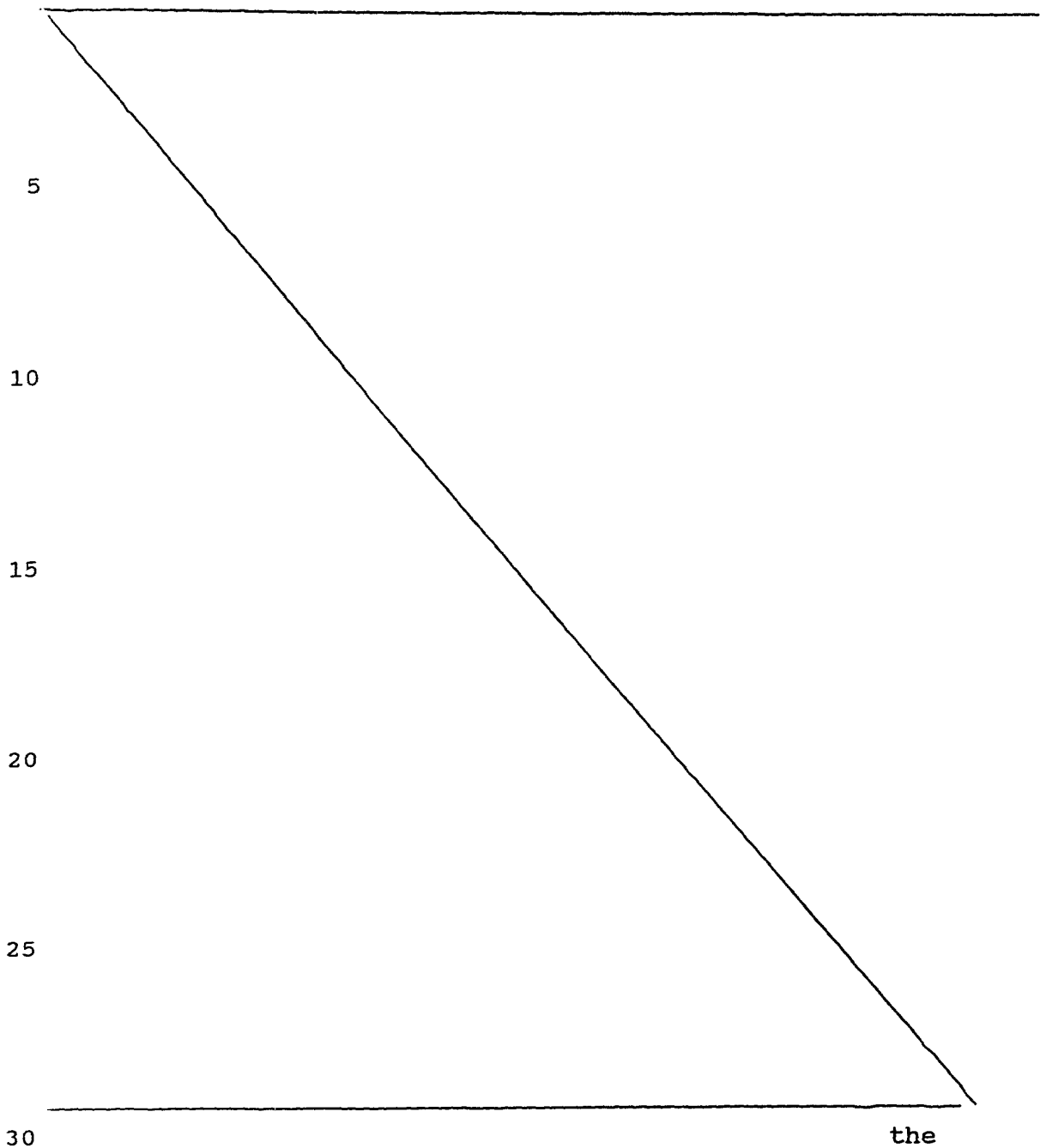
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Morris Liss

Date: 4/8/98

ABSTRACT OF THE DISCLOSURE

A needleless jet injection device including a barrel fitted with a cap at one of the ends thereof. Relative motion of the cap component actuates a setting device operably connected to a percussive member. A cartridge arranged at the other end of the barrel comprises two elements, i.e., a first element forming a container for the active principle, and a second element consisting of a plastic shell enclosing the first element.



pistol includes a breech or a magazine containing a cartridge, also placed in the axis of the striker.

Thus, the document WO 95/03844 discloses a device for injection by jet without needle, which is provided with an arming device activated by the rotation of a cap situated at one of the ends of the body of the said device.

The document WO 95/27523 describes a device for injection by jet without needle, provided at one of its ends with a cartridge formed in one piece.

5 The document WO 96/15821 describes a cartridge including a capsule on which a sleeve tube is fitted by force and induces stresses on the capsule.

10 Finally, the document EP 427 457 describes a device for injection by jet without needle, provided with a cartridge which cooperates at one of the ends of the device, by way of a component forming a breech.

15 Given the mode of action of the striker, which has a substantial kinetic energy before reaching the plunger of the cartridge, which can, in cases where the cartridge is not correctly arranged in the magazine of the pistol, cause it to burst at the start of the injection, these apparatuses are not reliable and are not easy to use if their use is infrequent.

20 The present invention is therefore aimed at overcoming these disadvantages by making available a device which is without magazine for a cartridge and which permits the injection by jet, without needle, of the product contained in a cartridge placed directly at the head of the said device, under strictly aseptic conditions, for a single use.

25 For this purpose, the cartridge for injection of a product, in particular a pharmaceutical product, by jet without needle, for single use, and intended to be fixed at a first end of the body of an injection device, the second end of the body receiving a cap which is able, by virtue of a relative movement of the body, to drive an arming device, cooperating with a percussion member intended to cooperate with the cartridge, is characterized in that it includes two elements:

35 - the first element made of glass forms the receptacle intended to contain the said product;

- the second element consists of an envelope of plastic material which is overmoulded on the said first element.

5 Other characteristics and advantages of the present invention will be evident from the description which follows, with reference being made to the attached drawings which show an illustrative embodiment of the invention, without this embodiment in any way being of a limiting character. In the figures:

50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99

- Figure 1 is a plan view, in front elevation and in section, of the device according to the invention, in the armed position;

5 - Figure 2 is a plan view, in front elevation and in section, of the device according to the invention, in the triggered position;

- Figure 3 is a view, on a larger scale and in section, of a cartridge containing a dose of injectable product;

10 - Figure 4 is a view illustrating another method of fixing the cartridge on the device;

- Figure 5 is a sectional view illustrating the movement of the striker on the elastomeric stopper contained in the cartridge;

15 - Figure 6 is a perspective view of the clamp system intended to hold the rod of the striker;

20 - Figure 7 is a plan view, in front elevation and in section, of the device according to another embodiment of the invention, including a releasable connection member;

- Figure 8 is a perspective view of the releasable connection member;

25 - Figure 9 is a plan view, in front elevation and in section, of the device according to the invention;

- Figure 10 is a plan view, in front elevation and in section, of a cartridge according to a second embodiment;

30 - Figure 11 is a plan view, in side elevation and in section, of a cartridge according to a second embodiment.

According to a preferred embodiment, the device which is the subject of the invention essentially comprises a body 1 extending in the form of a tube, in particular of straight cylindrical cross-section, intended to receive an arming device 2 connected to a cap 3, in particular knurled in order to improve its grip by the user, provided at one of the ends 4, 5 of the said body. The cap is made from a tube portion, of similar cross-section to that of the main body of the

35
40

1 said device, the diameter of which, however, is greater
in order to permit a relative rotational movement
thereof about the body, and it cooperates by way of a
catch device 6, in particular of the key type, with a
5 ring 7, itself integral with a clamp 8. The said ring
is engaged with play at the end of the body 1 and can
turn freely in the latter, its axial position in the
tube being determined by a radial abutment 9 on the
wall of the tube and fitting in a circular groove 10
10 formed on the said ring 7 and positioned opposite the
abutment 9. The rotational movement from the cap 3 is
transmitted to the ring by way of the catch device 6.
The said ring 7 is additionally provided with a central
recess 11 for the passage of a striker 12, free in
15 axial translation and leading inside the said clamp 8.
This clamp constitutes one of the links of the arming
device. Of overall cylindrical shape, it is equipped
with a plurality of cutouts 13 oriented substantially
parallel to the axis of the body in such a way as to
20 form a plurality of flexible tabs 14. In addition, the
inner bore 15 of the said clamp 8 is tapped in such a
way as to form impressions which can be screwed around
a threaded portion 16 provided on a rod 17 forming a
striker. The thread pitch is determined as a function
25 of the chosen demultiplication and the stiffness
constant of a spring 18. The power of the striker can
also be adjusted by means of pre-setting the
compression of the spring, it being possible for the
space between the turns to be set by way of a knurled
30 wheel 46 displaced on the rod 17 and in contact with 18
or by way of a stack of washers arranged between the
spring 18 and a ring 25. The turns of the spring 18 are
compressed by the relative rotational movement between
the cap 3 and the body 1.

35 According to an advantageous characteristic of
the invention, the cap 3 includes a safety device 47
which covers the rod of the striker 12. This safety
device 47 is connected to the cap 3 by way of a hinge
48 which permits a rotational movement of the latter
40 47, between a locked position and an unlocked position

of the rod of the striker 12. The rotation of the safety device 47 also makes it possible to act on the catch member 6 between the cap 3 and the ring 7. This is because it is essential that the user can arm the percussion device only when the safety device 47 is covering the rod of the striker 12; this is why, when the safety device 47 is locked on the cap 3, it acts on the catch member 6 in such a way that the latter permits the transmission of the rotational movement between the cap 3 and the ring 7.

When the safety device 47 is unlocked, that is to say when it is no longer covering the rod of the striker 12, it no longer acts on the catch member 6 and the user cannot arm the percussion device.

There is therefore a rod 17, forming a plunger, arranged inside the said body 1, its length being chosen in such a way that its end 19, not connected to the said clamp 8, is flush with one of the front surfaces 4, 5 of the body 1 when the arming device 2 is operational.

The peripheral envelope 20 of the clamp is held by a spacer sleeve 21, also of a cross-section similar to that of the body, the external diameter of which corresponds to the internal diameter of the body in such a way as to form guide zones. Its axial position inside the body being limited, on the one hand, at one of its ends 23, 24, by a pin 22 passing radially right through the striker 12, and, on the other hand, its other front end constituting a bearing surface for a spring 43; the axial position of the spring and its other bearing surface being additionally limited, for example, by a ring 25 inserted in the body, integral with the said rod 17 and axially immobilized, if appropriate, by a clip ring 26, or by a shoulder formed on the rod.

In the arming position, the user imparts a relative rotational movement between the body 1 and the cap 3; as we have seen above, the rotational movement of the cap is transmitted both to the said ring 7 and to the clamp 8 integral with the latter; the several

threads of the said clamp 8 in engagement with those of the rod make it possible to initiate the movement of translation between the rod 17 (forming the screw) and the clamp 8 (forming the nut) and the relative closing-together of these two components. This translation movement compresses the turns of the spring 18 until the space between the turns is reduced to the maximum. According to another embodiment, the spiral spring can be replaced by a helical spring or by any other elastic device.

In the disarm or trigger position, the user exerts a slight push on the striker 12, the pin 22, projecting radially and in contact with one of the front faces 23, 24 of the spacer sleeve, transmits a relative movement of translation between the spacer sleeve 21 and the clamp 8, which releases the end thereof from a conical bearing surface 27 provided at the bottom of the bore of the said spacer sleeve 21. The thrust of the spring 18 combined with the flexibility of the tabs of the clamp frees the respective threads previously in engagement, thereby provoking an almost impulse movement of translation of the whole rod.

According to another embodiment of the invention, there is arranged, between the cap 3 and the arming member integral with the clamp 8 contained in the body 1, a connection member 38 which permits the relative rotational movement between these two components only in one direction of rotation. The reason is that, to avoid any damage to the apparatus and to simplify its handling by the user, a releasable connection member 38 is provided which is composed principally of two components 39, 40, in particular of circular cross-section. One of the components 39 is integral with the cap 3, while the other 40 is connected to the clamp 8 and to the body 1 by way of a groove 44, and each of the components also has, at their contact face, a plurality of raised zones 41. These zones 41 have a profile which is able, on the one hand, to permit a relative sliding between the

components 39 and 40 in one direction of rotation between the cap 3 and the body 1 and, on the other hand, to transmit the moment in the other direction of rotation of the cap 3 relative to the body 1.

5 The raised zones 41 are preferably formed from a plurality of teeth, in particular of triangular cross-section.

For the connection member 38 to function, however, it is best not to suppress completely the movements of the components 39 and 40 in relation to the cap 3 and to the clamp 8; thus, when the connection member is active (released), it is necessary for the components 39, 40 to escape longitudinally from one another and for these components to return to their engaged position after suppression of the moment; for this reason, an elastic member 41, in particular of the spring type, is arranged in line with the outer surface of one of the components 39 or 40, in the area of a guide portion 42, which compensates for the translation movements between the components.

According to another characteristic of the invention, a cartridge 28 is arranged at the other end 5 of the body 1 of the said device, by known means such as, in particular, being screwed on, clipped on (bushing, bayonet).

According to an advantageous characteristic of the invention, the cartridge 28 includes two elements 49, 50:

- the first element 49 forms the receptacle intended to contain the active principle, and it is obtained in particular from a type I medical-grade glass, since the receptacle is to contain injectable products;

- the second element 50 consists of an envelope of plastic material which covers the said first element 49.

The plastic material used in the overmoulding, that is to say covering, operation must be able to withstand a sterilization operation at high temperature (in the region of 120°C), must be approved for

pharmaceutical applications, must be insensitive to the temperature deviations in terms of its expansion, given that the cartridges 28 are generally stored in an atmosphere where the temperature is between 2 and 10°C.

5 Moreover, after overmoulding on the first element 49, the plastic material employed is translucent, even transparent, and can be tinted. The product called _TPX_ (polymethylpentene) will be chosen, for example, as the plastic material.

10 The first element 49 made of glass, and overall of substantially cylindrical shape, includes, at each end, an orifice 29, 30. One 30 of the orifices has a diameter substantially equivalent to the diameter of the rod 17, while the other 29, of small diameter, in
15 particular of the order of a few tenths of a millimetre, serves as nozzle. The internal cavity of the said cartridge is filled under vacuum with an active principle 31 and is, if appropriate, covered with a film 32 of material compatible with the physico-
20 chemical properties of the said product, in order to limit to the maximum the phenomenon of adsorption.

The cartridge 28, thus formed by the overmoulding of a plastic material on a first element 49 made of glass, includes, at one of its ends, means
25 51 permitting the engagement and fixing of the said cartridge on the nose of the injection device.

The means 51 permitting the engagement and fixing are advantageously formed during the over-
moulding operation by way of a plurality of studs 52
30 which project radially and are arranged along the diameter of the said cartridge 28, these studs cooperating with the bayonets provided at the end 53 of the injection device.

The other end 54 of the said cartridge 28 is
35 designed as a plane surface intended to be applied against the surface of the skin of the user.

The outlet orifice 31 formed on this end 54 must be protected from possible contamination by the surrounding environment, and for this purpose there is

a cap 55 which is provided at its centre with an elastomeric seal 56, in particular of silicone.

According to another embodiment, a film covering the surface of the cartridge 28 is arranged on the end 54.

This cap 55 is obtained by a process of moulding of plastic material, if appropriate, similar to that forming the cartridge.

The cap 55 advantageously has lateral walls 57 which enclose the end of the said cartridge 28, the said walls 57 being provided, at their ends, with raised zones 58 allowing them to be clipped into impressions 59 provided on the outer lateral walls of the said cartridge 28, thus ensuring that the cap 55 is held on the cartridge.

The upper wall 60 of the cap 55 forms a grip zone which allows the user to position the studs 52 of the cartridge 28 in line with the bayonets of the injection device and, by a simple movement of rotation, to block the studs 52 in the bayonets and, after blocking the studs 52, when the user continues to impart this rotational movement to the cap 55 and thus to the cartridge 28 which is integral with it, to detach the lateral walls 57 of the cap 55 from the impressions 59 in the cartridge 28, in such a way as to make the injection device ready for use.

According to a first alternative, the elastomeric seal 56 is obtained during a simultaneous operation of moulding of the cap 55.

According to a second alternative, the elastomeric seal 56 is attached and fitted by force into an orifice 61 provided on the internal wall 62 of the cap 55.

According to another advantageous characteristic of the invention, it is intended to form a plurality of plastic material gaps in the thickness of the plastic overmould of the cartridge 28, in order to produce slots 63 for improving the visibility of the first element 49 made of glass. The cartridge 28 thus obtained is for single use and is therefore disposable.

After filling, the orifice 30 of the cartridge is closed off by a protective cover 33 in order to guarantee satisfactory aseptic conditions. It is also intended to interpose, between the dose of product
5 contained in the cavity of the cartridge and the protective sealing cover, an elastomeric stopper 34 for enclosing the dose, this stopper 34 being intended to communicate to the liquid the pressure exerted by the plunger of a striker.

10 According to an advantageous characteristic of the invention, the plunger of the striker is driven a few millimetres into the body of the cartridge so that the percussion force is directed and centred in the axis of the elastomeric stopper 34, in order to prevent
15 any risk of bursting of the first glass element forming the cartridge 28.

According to another embodiment of the cartridge 28, the latter is empty and is filled by the user just before use.

20 The outer envelope of the said cartridge moreover has, on the one hand, means of fixing 35, 35' to the said body (screw pitch, spike, etc.) and, on the other hand, raised zones 36 allowing it to be gripped by the user. The front face corresponding to the nozzle
25 comprises, if appropriate, a basin 37 whose depth is variable but guarantees that the jet issuing from the orifice of the nozzle has the time needed to establish its hydrodynamics prior to the subcutaneous, intra-dermal or intramuscular injection.

30 The invention, as it has been described above, is very easy to use: there is no more sterilization, nor washing of the apparatus, while at the same time increased safety for the user is guaranteed because of the absence of a needle and the impossibility of
35 reusing it without first having reloaded the apparatus with a new dose, the method of fixing the cartridge avoiding all the risks of the latter bursting because of the absence of a breach. This invention is advantageously adapted for use by a single user having
40 no specific knowledge in the field of subcutaneous,

intradermal or intramuscular injections, and it reduces, on the one hand, the risks of accidents, which are always possible with an injection means having a needle, and, on the other hand, it eliminates the fear of stick injuries and any risk of contamination. The use of this device also allows the patient's chronobiology to be taken into consideration. This invention will have advantageous developments in the injection of a dose of small volume, in particular of 0.05 to 0.2 ml. It is of special interest for the administration of medicaments or vaccines to man or animals. Among other products which may be mentioned are polypeptides or peptides, such as enzymes and particularly calcitonin, used for the prevention of loss of bone substance and the treatment of osteoporosis, or else medicaments against migraine. Other products, in particular polypeptides or peptides, which may be administered using the device forming the subject of the invention, include hormones, such as insulin, somatostatin, the growth hormone, clotting factors, for example antihaemophilic factors, plasma components, such as erythropoietin, antiviral polypeptides, such as interferons, or immunomodulators, such as lymphokines. This device is also especially appropriate for the administration of vaccine preparations.

Of course, the present invention is not limited to the illustrative embodiments which have been described and represented above, but can encompass all variants thereof. Thus, the cartridges can be presented before the rod of the striker with the aid of a barrel or a charger, and they can also comprise the dose of the product to be injected.

CLAIMS

1. Cartridge (28) for injection of a product, in
5 particular a pharmaceutical product, by jet without
needle, for single use, and intended to be fixed at a
first end (5) of the body (1) of an injection device,
the second end (4) of the body (1) receiving a cap (3)
which is able, by virtue of a relative movement of the
10 body (1), to drive an arming device (2), cooperating
with a percussion member (17) intended to cooperate
with the cartridge (28), is characterized in that it
includes two elements (49, 50):

- the first element (49) made of glass forms
15 the receptacle intended to contain the said product;
- the second element (50) consists of an
envelope of plastic material which is overmoulded on
the said first element (49).

2. Injection cartridge according to Claim 1,
20 characterized in that the first element (49) is
obtained using a type I medical-grade glass.

3. Injection cartridge according to Claim 1,
characterized in that the second element (50) is made
of a plastic material which possesses the following
25 characteristics:

- withstands a sterilization operation at high
temperature,
- is approved for pharmaceutical applications,
- is insensitive to the temperature deviations,
30 - is translucent, even transparent, and, if
appropriate, tinted.

4. Injection cartridge according to Claim 1,
characterized in that the first element (49), overall
of substantially cylindrical shape, includes, at each
35 end, an orifice (29, 30), one (30) of the orifices
having a diameter substantially equivalent to the
diameter of a rod (17) of the percussion member, while
the other (29), of small diameter, in particular of the

order of a few tenths of a millimetre, serves as nozzle.

5. Injection cartridge according to any one of the preceding claims, characterized in that it includes, at
5 one of its ends, means (51) permitting the engagement and fixing of the said cartridge on the nose of the injection device.

6. Injection cartridge according to Claim 5, characterized in that the means (51) permitting the
10 engagement and fixing are formed during the covering, overmoulding operation by way of a plurality of studs (52) which project radially and are arranged along the diameter of the said cartridge (28), these studs cooperating with the bayonets provided at the end (53)
15 of the injection device.

7. Injection cartridge according to any one of the preceding claims, characterized in that the end (54) of the cartridge (28) is covered by a cap (55) provided at its centre with an elastomeric seal (56), in particular
20 of silicone.

8. Injection cartridge according to Claim 7, characterized in that the cap (55) has lateral walls (57) which enclose the end of the said cartridge (28), the said walls (57) being provided, at their ends, with
25 raised zones (58) allowing them to be clipped into impressions (59) provided on the outer lateral walls of the said cartridge (28), thus ensuring that the cap (55) is held on the cartridge.

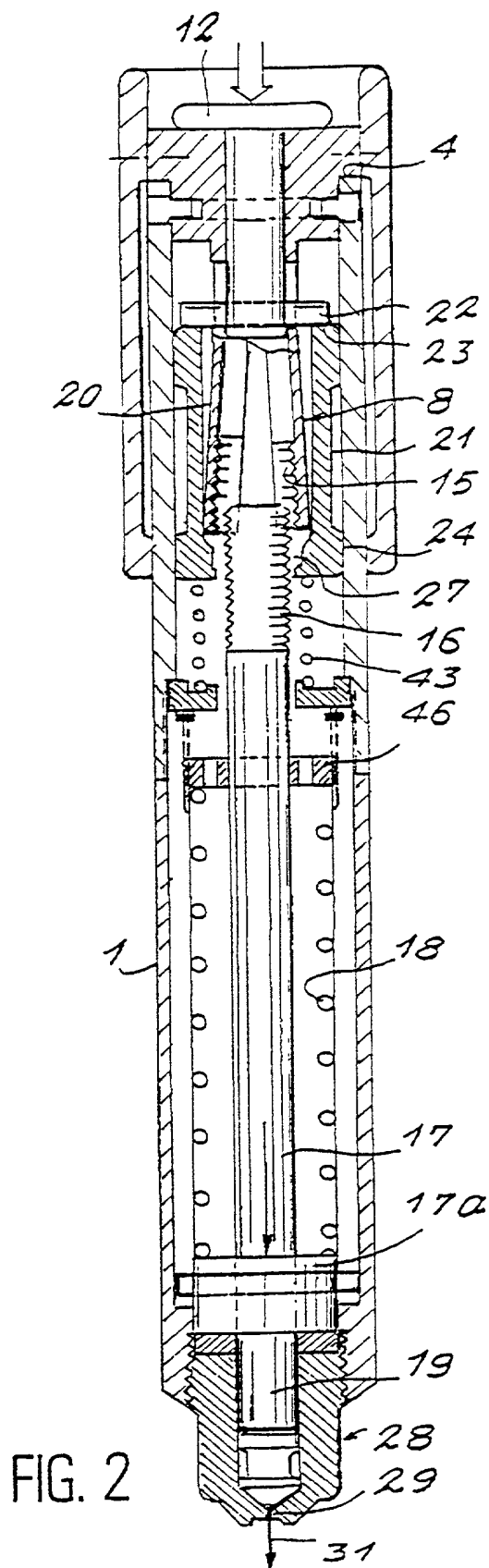
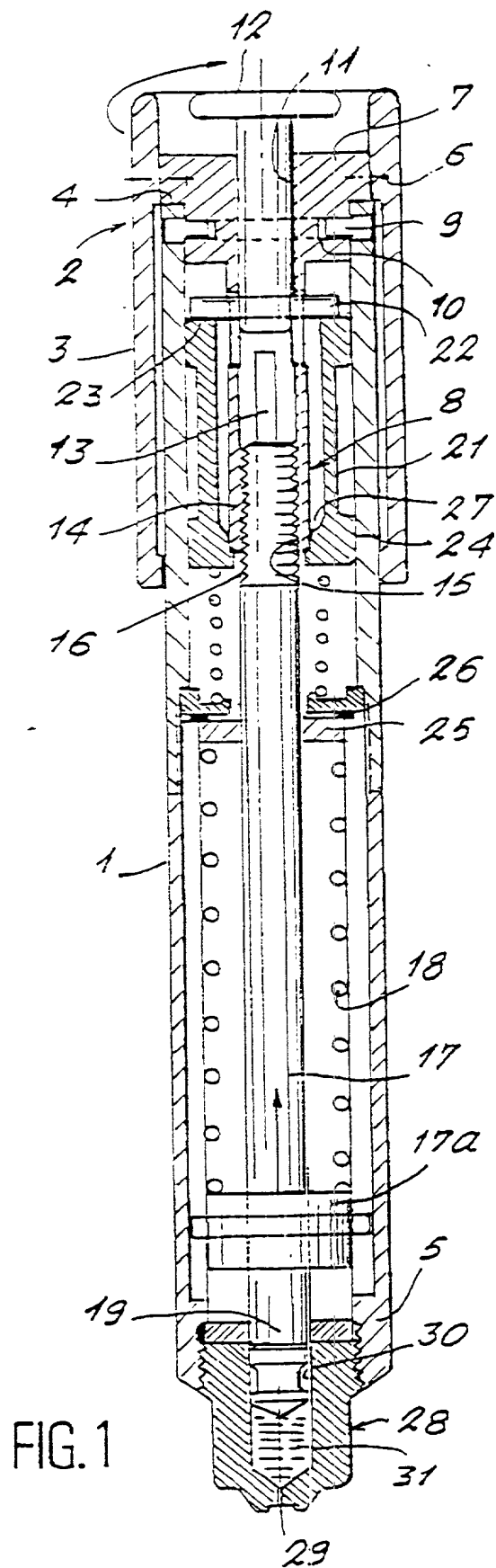
9. Injection cartridge according to one of Claims
30 7 and 8, characterized in that the upper wall (60) of the cap (55) forms a grip zone which allows the user to position the studs (52) of the cartridge (28) in line with the bayonets of the injection device.

10. Injection cartridge according to Claim 7,
35 characterized in that the elastomeric seal (56) is obtained during a simultaneous operation of moulding of the cap (55).

11. Injection cartridge according to Claim 7, characterized in that the elastomeric seal (56) is

attached and fitted by force into an orifice (61) provided on the internal wall (62) of the cap (55).

12. Injection cartridge according to any one of the preceding claims, characterized in that it includes a
- 5 plurality of plastic material gaps, formed in the thickness of the plastic overmould of the cartridge (28), in order to produce slots (63) for improving the visibility of the first element (49).



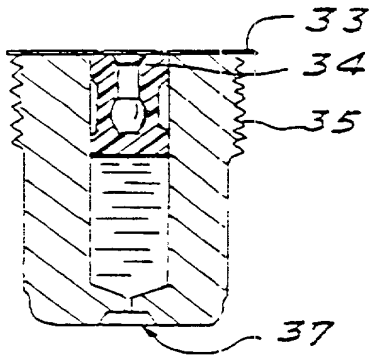


FIG. 3

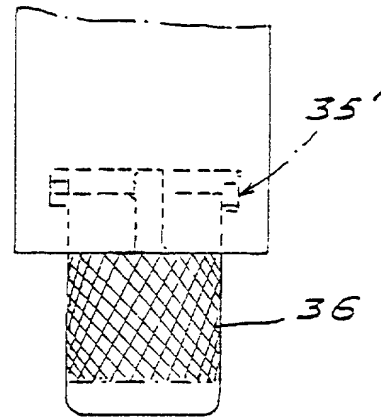


FIG. 4

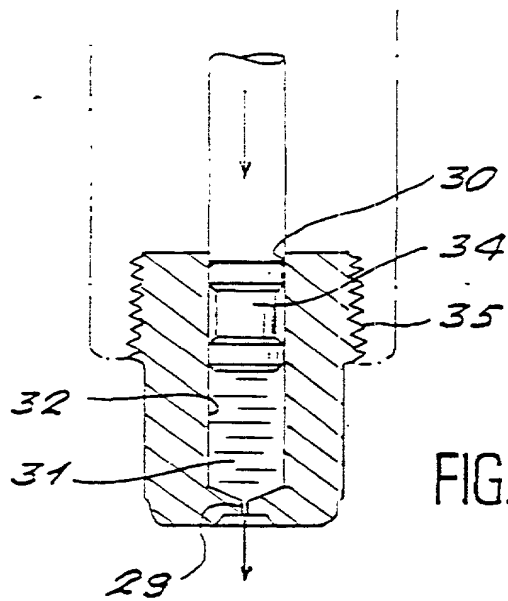


FIG. 5

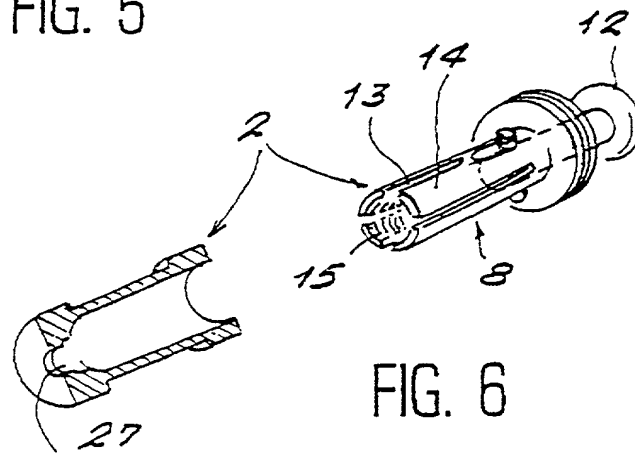


FIG. 6

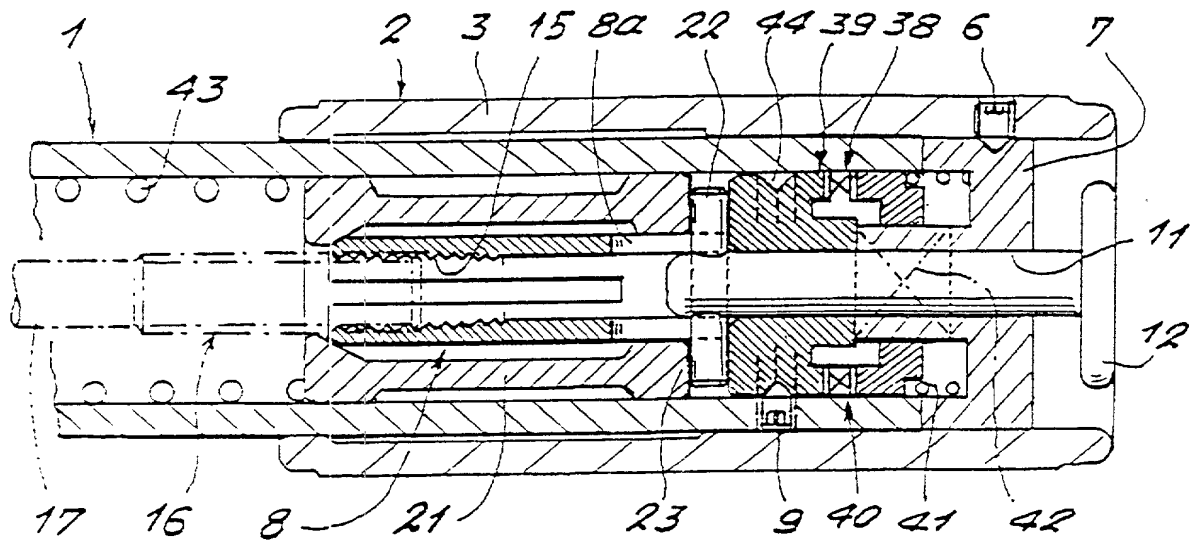


FIG. 7

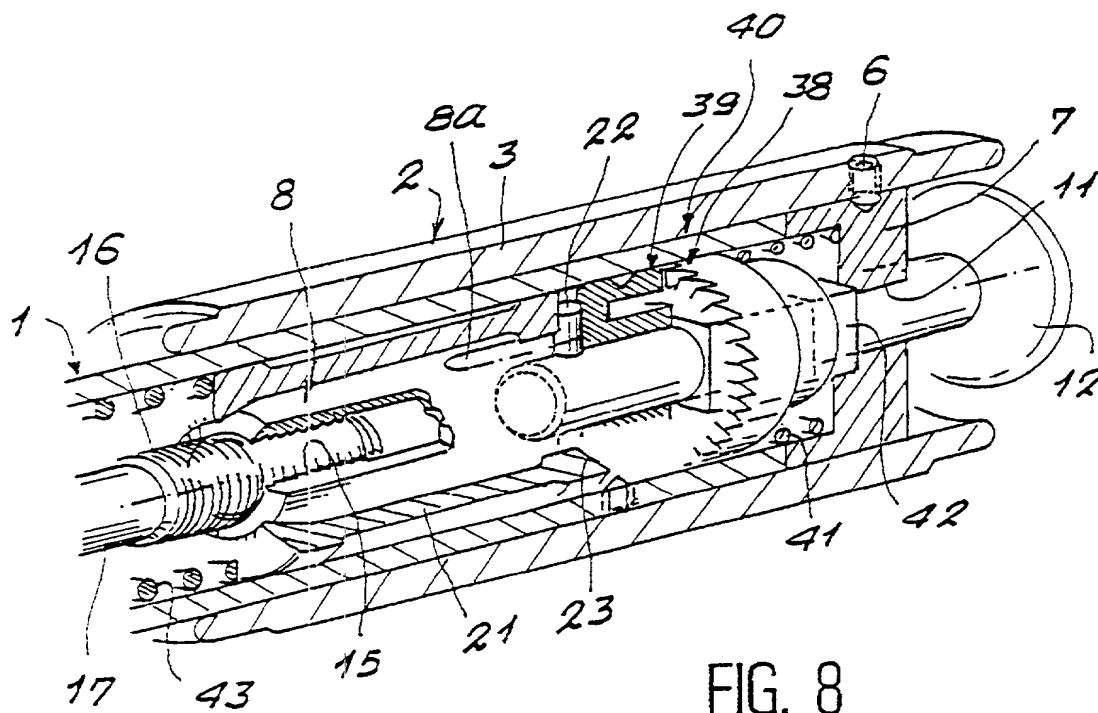


FIG. 8

FIG. 9

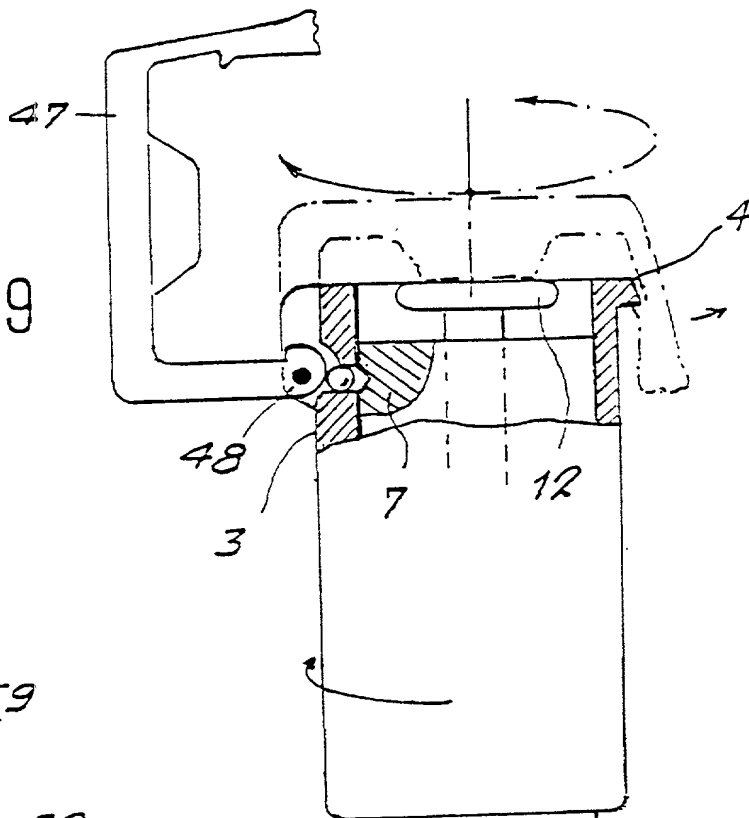


FIG. 10

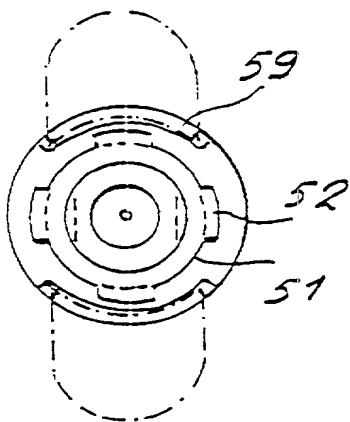
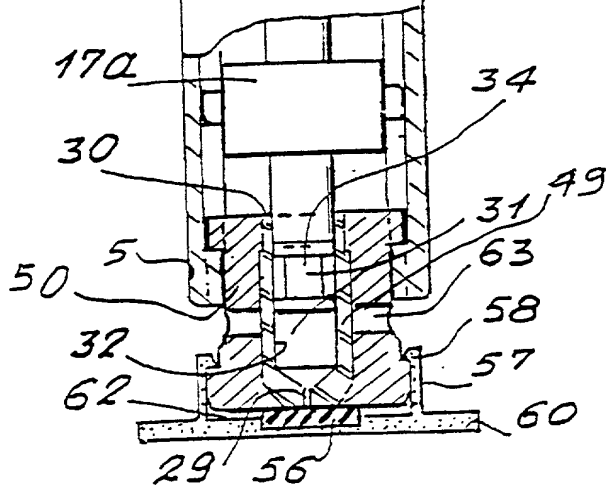
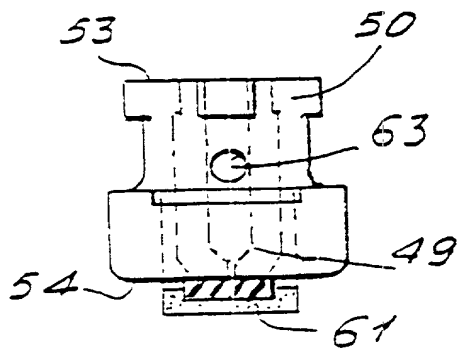


FIG. 11



DECLARATION FOR PATENT APPLICATION

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Needleless jet injection device comprising a moulded-on cartridge.
the specification of which: (check one)

☐ is attached hereto. ☒ was filed on October 9, 1996, as United States Patent Application Serial No. or PCT International Application Number PCT/FR96/01573, and was amended on September 18, 1997.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 CFR § 1.56(a).

Prior Foreign Application(s): I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate listed below, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

			Priority Claimed
<u>95 11872</u>	<u>FRANCE</u>	<u>9 October 1995</u>	<input checked="" type="checkbox"/> <input type="checkbox"/>
(Application No.)	(Country)	(Day/Month/Year Filed)	Yes No
<u></u>	<u></u>	<u></u>	<input type="checkbox"/> <input type="checkbox"/>
(Application No.)	(Country)	(Day/Month/Year Filed)	Yes No
<u></u>	<u></u>	<u></u>	<input type="checkbox"/> <input type="checkbox"/>
(Application No.)	(Country)	(Day/Month/Year Filed)	Yes No

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date
<u></u>	<u></u>
<u></u>	<u></u>

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by 35 U.S.C. § 112, first paragraph, I acknowledge the duty to disclose material information as defined in 37 CFR § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(U.S. Application Serial No.)	(U.S. Filing Date)	(Status--patented, pending, abandoned)
<u></u>	<u></u>	<u></u>
(U.S. Application Serial No.)	(U.S. Filing Date)	(Status--patented, pending, abandoned)

I hereby appoint Elliott I. Pollock, Registration No. 16,906; George Vande Sande, Registration No. 17,276; Robert R. Priddy, Registration No. 20,169; Burton A. Amernick, Registration No. 24,852; Stanley B. Green, Registration No. 24,351; Richard Wiener, Registration No. 18,741; Townsend M. Belser, Jr., Registration No. 22,956; Morris Liss, Registration No. 24,510; Martin Abramson, Registration No. 25,787; George R. Pettit, Registration No. 27,369; Louis Woo, Registration No. 31,730; Elzbieta Chlopecka, Registration No. 32,767; Eric J. Franklin, Registration No. 37,134; and Robert Scott Wales, Registration No. 39,413, my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Send Correspondence and Direct Telephone Calls to:
Morris Liss
(202) 331-7111

Morris Liss
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Washington, D.C. 20036-3425 U.S.A.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature [Signature] Date
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[] See next page for additional inventors

DECLARATION FOR PATENT APPLICATION

Page Two

200 Full name of second joint inventor (if any): Mr MOREAU DEFARGES Xavier

Inventor's Signature [Signature] Date _____

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Citizenship French FRX

Post Office Address 80 Rue de la Liberté 92150 SURESNES FRANCE

Full name of third joint inventor (if any): _____

Inventor's Signature _____ Date _____

Residence Address _____

Citizenship _____

Post Office Address _____

Full name of fourth joint inventor (if any): _____

Inventor's Signature _____ Date _____

Residence Address _____

Citizenship _____

Post Office Address _____

Full name of fifth joint inventor (if any): _____

Inventor's Signature _____ Date _____

Residence Address _____

Citizenship _____

Post Office Address _____

Full name of sixth joint inventor (if any): _____

Inventor's Signature _____ Date _____

Residence Address _____

Citizenship _____

Post Office Address _____

Full name of seventh joint inventor (if any): _____

Inventor's Signature _____ Date _____

Residence Address _____

Citizenship _____

Post Office Address _____

Full name of eighth joint inventor (if any): _____

Inventor's Signature _____ Date _____

Residence Address _____

Citizenship _____

Post Office Address _____

Applicant or Patentee: Alain Moreau Defarges Attorney's
Serial or Patent No.: 09/051,290 Docket No.: 1029/168
Filed or Issued: April 8, 1998
For: Needleless jet injection device comprising a moulded-on cartridge.

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled

described in:

- ☐ the specification filed herewith
- ☐ application serial no. _____, filed _____.
- ☐ patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted conveyed, or licensed or am under an obligation under contract to law to assign, grant, convey, or license any rights in the invention is listed below:

- ☐ no such person, concern, or organization
- ☐ persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

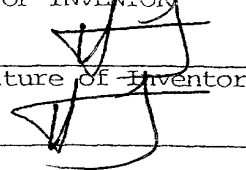
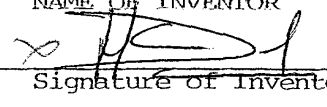
FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
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FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

MOREAU DEFARGES Alain	MOREAU DEFARGES Xavier	
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
		
Signature of Inventor	Signature of Inventor	Signature of Inventor
Date	Date	Date